

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF TEXAS  
LUBBOCK DIVISION**

**STATE OF TEXAS,**  
*Plaintiff,*

v.

**PFIZER, INC.,**  
*Defendant.*

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**NO. 5:23-cv-00312-C**

**OPPOSITION TO MOTION TO DISMISS**

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## INTRODUCTION

In 2021, capitalizing on Americans’ fear of the unknown in the early days of the COVID-19 pandemic, Pfizer touted its new vaccine as a miracle cure. FDA had just granted Pfizer an emergency use authorization for its vaccine in December 2020—a regulatory action the State of Texas does not challenge. But when FDA granted that authorization, it did so with several important caveats. First, at the time, it was “not possible” to know how effective the vaccine was beyond two months, because Pfizer had only two months of clinical data on infection rates after vaccination. Compl. ¶ 49.A. Second, FDA made clear that Pfizer “needed” additional evidence to prove its vaccine protected against “virus shedding and transmission” of COVID-19 to others. *Id.* ¶ 49.C. Lastly, Pfizer’s clinical trial assessed its vaccine’s efficacy against the original strain of the virus only, not against mutations such as the more potent Delta strain. *Id.* ¶ 84.

Yet within weeks, Pfizer’s CEO, Albert Bourla, went on major news networks promoting that the company’s vaccine possessed the very qualities FDA told Pfizer it had not shown. Texans heard that “at 6 months, the protection [of the Pfizer vaccine] is robust”—despite Pfizer only having 2 months of data. *Id.* ¶ 76. Texans heard that getting the Pfizer vaccine prevented transmission and that vaccination was necessary to protect “the people you love most”—despite Pfizer lacking any data on the subject. *Id.* ¶ 67. And Texans heard Pfizer’s CEO publicly insist that the company’s vaccine was “very, very, very effective against Delta”—despite Pfizer having little to no clinical data on Delta. *Id.* ¶ 88.D.

Worst of all, though, was Pfizer’s trademark marketing line: That its vaccine was “95% effective.” That claim was highly misleading from the jump. It represented a calculation of so-called “relative risk reduction” for vaccinated individuals in Pfizer’s then-unfinished two-month clinical trial. But FDA finds that statistic misleading, and prefers drug manufacturers to advertise

*absolute* risk reduction: The *actual decrease* in risk between getting a treatment or not. Pfizer’s clinical trial showed *absolute* risk reduction of only **0.85%**. Compl. ¶ 45. In other words, the Pfizer vaccine reduced a person’s risk of getting COVID-19 by less than one percent. All of Pfizer’s many misrepresentations to the public failed to mention this.

It is now also beyond cavil that Pfizer’s unsubstantiated claims ultimately turned out to be false. Countless vaccine recipients contracted COVID, many died, and at least some data shows that the vaccinated experienced worse outcomes than the unvaccinated. Compl. ¶ 114–15. But when some scientists, including a former FDA chief, tried to push back on Pfizer’s claims, Pfizer engaged in a scheme to censor those individuals—all to gain and maintain market share for a vaccine that earned it tens of billions of dollars in profit. Taken together, Pfizer’s misrepresentations and censorship scheme were misleading and deceptive, and they harmed Texas and its citizens. They are bread-and-butter violations of the Texas Deceptive Trade Practices Act (DTPA) and not subject to dismissal on the pleadings.

Unable to challenge the State’s well-pled claims of misleading conduct and deceptive conduct, Pfizer’s Motion to Dismiss rests on portraying the State’s lawsuit as something that it is not, namely: A challenge to FDA’s regulatory decision to approve Pfizer’s vaccine. *See* Mot. at 18 (“OAG’s complaint second guesses FDA’s decision making . . .”). In reality, the State’s complaint raises no objection to FDA’s approval of Pfizer’s vaccine, and in fact *agrees* with the agency’s official stance in several important respects, such as the deceptive nature of the relative risk reduction statistic and Pfizer’s lack of clinical evidence for many of its public statements.

Nevertheless, Pfizer contends that the Public Readiness and Emergency Preparedness (PREP) Act and Federal Food, Drug, and Cosmetic Act (FDCA) preempt the State’s DTPA claims. But the PREP Act preempts only state laws “different from, or in conflict with” federal law, and

federal law explicitly “made it illegal ‘for any[one] to engage in a deceptive act or practice in or affecting commerce . . . associated with the treatment, cure, prevention, mitigation, or diagnosis of covid-19.’” *FTC v. Romero*, 2022 WL 4095424, at \*4 (M.D. Fla. June 29, 2022) (citation omitted). Far from being “different from, or in conflict with” federal law, the State’s DTPA claims *mirror* federal law. Similarly, Pfizer’s argument that the FDCA preempts the DTPA claims fails because Congress intentionally crafted the FDCA to *not* preempt state claims against drug manufacturers. *See Wyeth v. Levine*, 555 U.S. 555, 574 (2009) (Congress “determined that widely available state rights of action provided appropriate relief for” drug manufacturers’ wrongdoings). Pfizer’s claim that the PREP Act provides immunity against State DTPA claims is also misplaced, because the PREP Act’s “immunity” provision extends only to personal injury “claims for loss” based on vaccine administration, not deceptive marketing *parens patriae* claims brought by a sovereign.

The Complaint’s voluminous detail also rebuts Pfizer’s argument that Texas failed to adequately plead a DTPA claim. The Court should deny Pfizer’s Motion to Dismiss and this lawsuit should go forward.

## **BACKGROUND**

### **A. Texas’s DTPA**

Texas’s DTPA protects consumers by prohibiting “[f]alse, misleading, or deceptive acts or practices in the conduct of any trade or commerce.” Tex. Bus. & Com. Code § 17.46(a) (hereinafter DTPA § 17.46(a)). Deceptive trade practices are defined broadly to include, among other things, “representing that goods or services have . . . uses, [or] benefits” “which they do not have,” *id.* § 17.46(b)(5); inducing consumers to enter transactions by “failing to disclose information concerning goods or services which was known at the time of the transaction,” *id.* § 17.46(b)(24); and “representing that goods or services are of a particular standard, [or] quality” if they are not of such standard or quality, *id.* § 17.46(b)(7). By statute, these categories “shall be liberally

construed.” *Id.* § 17.44(a); accord *Weitzel v. Barnes*, 691 S.W.2d 598, 600 (Tex. 1985) (the DTPA’s “broad guidelines” must be “liberally construed to protect consumers from deceptive business practices”).

The Texas Attorney General—through the Consumer Protection Division—has *parens patriae* authority to enforce the DTPA whenever it “has reason to believe” unlawful conduct is occurring. DTPA § 17.47(a). The Division can seek injunctive relief, *id.* § 17.47(a); civil penalties up to “\$10,000 per violation,” *id.* § 17.47(c); and restitution and disgorgement, *id.* § 17.47(d). When the Division brings an enforcement action, it “acts in the name of the State and does not” represent any individual injured person(s). *Id.* § 17.47(h).

## **B. Federal Regulatory Framework**

FDA must approve any new drug prior to that product’s commercialization. 21 U.S.C. § 355 (drugs); 42 U.S.C. § 262 (biologics); accord Compl. ¶ 10 n.1 (defining biologics). FDA also has authority to issue an “Emergency Use Authorization” (EUA), which is not a formal approval, but which nevertheless allows a drug product to come to market if the Secretary of Health and Human Services declares an emergency. 21 U.S.C. § 360bbb-3.

Approval Standards: Ordinarily, FDA “shall” deny approval if “there is a lack of substantial evidence that the drug *will have* the effect it purports or is represented to have.” 21 U.S.C. § 355(d)(5) (emphasis added). But the EUA process is laxer. For EUAs, FDA may grant authorization if the product “*may* be effective.” *Id.* § 360bbb-3(c)(2)(A). In FDA’s own words, the EUA process “provides for a lower level of evidence” of “effectiveness,” Compl. ¶ 13. (quoting FDA published guidance), and the agency recognizes it grants EUAs based on incomplete information. *Id.* at ¶¶ 13-19.

Clinical testing: Generally, after obtaining preliminary sign-off from FDA, drug manufacturers initiate lengthy “clinical testing” “for safety and effectiveness.” *Abigail All. for*

*Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 698 (D.C. Cir. 2007). In a nutshell, this consists of phased testing on humans in order to measure a drug’s safety and effectiveness. *See id.*; Compl. ¶ 16 (describing phases in detail). This is an arduous, time-consuming process—at least one study showed new drug development takes on average over eight years to complete. *Id.* ¶ 17. By contrast, FDA subjects EUAs to materially different standards. For example, the agency does not require “adequate and well-controlled clinical trials”; rather, as part of FDA’s overall more *ad hoc* and less formalized process, clinical data need only be submitted “if available,” 21 U.S.C. § 360bbb-3(c)(2).

For these reasons and more, Congress has understood that EUAs will have inferior guarantees of safety and efficacy compared to formally approved drugs. Compl. ¶ 14. Accordingly, Congress mandated that FDA directly inform health care providers of any “significant known and potential benefits and risks” of EUA products. 21 U.S.C. § 360bbb-3(e)(1)(A)(II). Similarly, and unlike with formal approvals, Congress directed FDA to provide individuals receiving an EUA product the same information. *Id.* § 360bbb-3(e)(1)(A)(II).

*Prohibitions on Misleading Marketing*: Federal law contains several prohibitions on misleading marketing that apply to drug products. For example, it prohibits “misbrand[ing],” *id.* § 331(c), which includes misleading labeling, as well as misleading “advertising,” *id.* § 331(n). The determination of whether a representation is misleading must take account of whether the manufacturer “fails to reveal material in light of representations” expressly made. *Id.* Additionally, the Federal Trade Commission (FTC) Act prohibits deceptive behavior in commerce generally. 15 U.S.C. § 45. And, critically here, the federal Covid-19 Consumer Protection Act expressly made the FTC Act’s ban on deceptive conduct applicable to *any* representations “associated with the treatment, cure, prevention, mitigation, or diagnosis of covid-19.” Public Law 116-260, 134 Stat.

1182, Title XIV, Section 1401(b)(1). Texas law functionally mirrors these prohibitions on misleading marketing. *See* Compl. ¶ 24. Indeed, Texas’s statutory bar on deceptive conduct specifically incorporates the FTC Act. DTPA § 17.46(a).

### C. Pfizer’s Limited Emergency Use Authorization

On November 20, 2020, Pfizer submitted an EUA request for its COVID-19 vaccine. Compl. ¶ 38.<sup>1</sup> That application relied principally on “safety and efficacy data from an ongoing” Phase 3 clinical trial. *Id.* As alleged in the Complaint, the specifics of that trial are germane to this proceeding because Pfizer went on to misrepresent its vaccine’s efficacy in ways contrary to the trial’s findings. *Id.* ¶¶ 38-39.

Pfizer’s Study Design & Protocol: Pfizer’s clinical trial enrolled over 40,000 people randomly divided into similarly sized placebo and treatment groups, with participants receiving “2 doses of either [the vaccine] or placebo, 21 days apart.” Compl. ¶ 39. The study was designed to test for “primary efficacy endpoints.” *Id.* ¶ 40. As relevant here, the first primary efficacy endpoint sought to measure the number of COVID-19 infections seven days after the second dose, among participants who had *not* been infected previously. *Id.* The trial’s definition of a COVID-19 case was not intuitive: If someone tested positive for COVID-19, that alone was *not* considered a COVID-19 case. *Id.* ¶ 42. Instead, to be considered a COVID-19 case, the positive test had to be accompanied by specific symptoms of infection. *Id.* (discussing study’s criteria for a “Defined COVID-19 Case”).

Pfizer’s Initial Results: In its EUA application, Pfizer submitted clinical trial data through November 14, 2020. *Id.* ¶ 44. At that point, Pfizer’s data was highly time limited—only 43.9% of

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<sup>1</sup> The Complaint relies on and incorporates by reference FDA’s Pfizer EUA. *See* FDA, *Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum* (Dec. 11, 2020), <https://www.fda.gov/media/144416/download>.

vaccine recipients had completed even two months of post-vaccination follow-up. *Id.* ¶ 43. The data showed that of 17,411 participants who received the vaccine and did not have evidence of a prior infection, 8 people (0.04%) met the study’s criteria for a COVID-19 infection. *Id.* ¶¶ 42, 44. On the other hand, out of the 17,511 participants who received the placebo and who lacked evidence of a prior infection, 162 participants (0.9%) met the relevant study criteria. *Id.* This is the genesis of Pfizer’s “95% effective” statistic—the difference in likelihood of a Defined COVID-19 Case based on 8 occurrences versus 162. *Id.* As explained *infra* at 8–9, this was a *caveat-laden* statistic, and one that did not support what Pfizer was telling the public. *Id.* ¶¶ 44–48.

*FDA’s Explicitly Limited Findings:* On December 11, 2020, FDA concluded that Pfizer’s data was adequate to support an EUA grant. *Id.* ¶ 48. However, FDA expressly stated that Pfizer’s results *did not* support making statements on several important efficacy dimensions relevant to Pfizer’s subsequent misrepresentations. First, FDA stated that based on the study’s results, “it is *not possible* to assess sustained efficacy [for Pfizer’s vaccine] over a period longer than 2 months.” *Id.* ¶ 49(A). And second, “[a]dditional evaluations . . . will be needed to assess the effect of the vaccine in preventing virus shedding and transmission,” in particular “the effect . . . against asymptomatic infection” on account of “limited” data. *Id.* ¶ 49(B)–(C). FDA recognized that Pfizer’s results were peculiar in other ways too. *See id.* ¶ 47 (noting how, between the first and second dose, more *vaccinated* persons contracted COVID-19 than unvaccinated persons).

**D. The Complaint’s Factual Allegations About Pfizer’s Serial Misrepresentations Concerning Its COVID-19 Vaccine.**

Notwithstanding the limited nature of Pfizer’s clinical trial data and scope of FDA’s EUA, Pfizer rapidly began making material misrepresentations about the vaccine in an attempt to gain market share and earn profits that would justify the enormous financial and reputational risk Pfizer took in developing a COVID-19 vaccine. Compl. ¶¶ 54–91. The State’s complaint alleges in great

detail how Pfizer made four different types of misrepresentations in a successful attempt to mislead the public about the efficacy of its vaccine, in violation of DTPA sections 17.46(b)(5) (representing a product has a use or benefit that it lacks), (7) (representing a product is of a particularly quality when it is not), and (24) (failing to disclose material information known at the time of a transaction). The complaint additionally pleads a fifth claim that Pfizer engaged in a scheme to conceal its vaccine's underperformance by censoring critics, in violation of DTPA section 17.46(b)(8) (disparaging another by false or misleading representation of facts).

(1) **“95% effective”:** From at least December 2020 and throughout 2021, Pfizer repeatedly issued press and other public statements touting the vaccine's alleged “95%” efficacy. Compl. ¶ 56-62. The media mimicked these representations, disseminating Pfizer's falsehoods over the globe. *Id.* ¶¶ 63–65. As is now well-known, the 95% efficacy statistic bore no resemblance to reality. *Id.* ¶¶ 94, ¶¶ 105–09. And, as alleged in detail in the State's Complaint, these representations were false, misleading, or deceptive *when made* in at least two ways.

*First*, Pfizer's 95% efficacy representation was misleading because it relied on a flawed method of expressing a drug's efficacy known as “relative risk reduction.” *Id.* ¶ 44; *id.* ¶¶ 25–34 (explaining that experts consider relative risk reduction statistics “meaningless and misleading”). FDA itself has explained in public guidance to industry that the statistic is often misleading because “[w]hen information is presented” in a “relative risk format,” the ostensible “reduction *seems* large and treatments are viewed more favorably” than warranted. *Id.* ¶¶ 25–31.<sup>2</sup> A host of scientific literature corroborates the propensity for the statistic to be “misused” by manufacturers to “exaggerate” a drug's benefits. Compl. ¶¶ 31, 34. And the overwhelming majority of

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<sup>2</sup> FDA, *Communicating Risks and Benefits: An Evidence-Based User's Guide* 56 (2011), <https://www.fda.gov/about-fda/reports/communicating-risks-and-benefits-evidence-based-users-guide> (FDA Risk Guidance).

pharmaceutical companies heed that advice, unlike Pfizer. A recent study by Yale Law and Medicine researchers found that in a sample size of 97 consumer advertisements for prescription drugs, *only one* presented “relative risk reduction” alone to convey efficacy.<sup>3</sup>

For these reasons, FDA’s official guidance instructs drug manufacturers and industry participants to “[p]rovide *absolute* risks, not just relative risks.” when describing efficacy. Compl. ¶ 31 (FDA Guidance at 56) (emphasis added)). Pfizer’s own data showed that the *absolute* risk reduction from its vaccine was *less than one percent*, *id.* ¶ 45, and that it was necessary to treat 119 people to prevent a single Defined COVID-19 Case, *id.* ¶ 46. Central to understanding these enormous discrepancies and their significance is the fact that very few participants in *either* the placebo *or* treatment groups actually contracted COVID-19 (as defined by the study). *Id.* ¶ 45. But Pfizer never said a word about absolute risk reduction to the public.

*Second*, Pfizer’s representations about 95% efficacy were deceptive because Pfizer presented them to the public in a manner materially different from how it measured efficacy in the clinical trial. For example, in public Pfizer touted the vaccine as “more than 90% effective in *preventing* COVID-19 in participants.” Compl. ¶ 56 (emphasis added). However, that is not what the trial actually measured. *Supra* at 6. Rather, Pfizer’s study was designed to count only participants who tested positive *and* showed certain symptoms. Compl. ¶ 42.

**(2) Transmission:** Pfizer also used deceptive and misleading tactics to create a public culture of fear and shame by convincing people that their own vaccination status would “affect the lives of others,” including “people you love the most.” Compl. ¶ 67; *see also id.* ¶¶ 66–72. Specifically, Pfizer represented to the public that “[w]idespread vaccination is a critical tool to

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<sup>3</sup> See Kristina Klara et al., *Direct-to-Consumer Broadcast Advertisements for Pharmaceuticals: Off-Label Promotion and Adherence to FDA Guidelines*, J. Gen. Intern. Med. 651 (May 2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5910340/>.

help stop transmission.” *Id.* ¶ 69. But Pfizer’s clinical trial did not support this fearmongering. After all, FDA recognized that “[a]dditional evaluations” would “be needed to assess the effect of the vaccine in preventing virus shedding and transmission.” *Id.* ¶ 49.D. Pfizer’s clinical trial simply was not designed to test for protection against transmission (or asymptomatic illness). *Id.* ¶ 42. Indeed, even when Pfizer obtained its formal vaccine approval in August 2021, FDA recognized that there were *still* no reliable indicators that the vaccine protected against “asymptomatic infection and transmissibility of the virus.” *Id.* ¶ 96. Moreover, significant public studies suggested that the vaccine did not protect against transmission at all. *Id.* ¶¶ 103–04.

**(3) Durability:** Pfizer also made a series of misrepresentations about the vaccine’s durability of protection. *Id.* ¶¶ 73–82. For example, in February 2021, Pfizer claimed that “at 6 months [from vaccination,] the protection is robust.” *Id.* ¶ 76. This was false. In February 2021, Pfizer did not even *have* 6 months of post-vaccination trial data. *Id.* ¶ 43 (mid-November 2020, Pfizer barely had two months of follow-up data). And FDA told Pfizer that “it [wa]s *not possible*” based on Pfizer’s then-existing data “to assess sustained efficacy over a period longer than 2 months.” *Id.* ¶ 49. Then, in March 2021, Pfizer’s own ongoing trial results revealed *substantial* waning efficacy. *Id.* ¶¶ 80, 94. But Pfizer withheld these results from the public until late July 2021. *Id.* ¶ 80. Global studies also revealed that the vaccine rapidly lost efficacy within mere months of the second shot. *Id.* ¶¶ 105–09. Nevertheless—and despite having actual knowledge of waning efficacy—Pfizer issued a series of deceptive statements to create the impression that durability was long-lasting, *id.* ¶¶ 77–79; and the press repeated these statements, *id.* ¶¶ 81–82.

**(4) Protection against variants:** Pfizer also made a host of misrepresentations about whether its vaccine would protect against COVID variants. *Id.* ¶¶ 83–91. Pfizer’s clinical trial did not evaluate efficacy against any variants. *Id.* ¶ 95 (FDA recognizing this). But that was a major

problem for Pfizer because, shortly after its EUA grant, multiple variants—including the notorious Delta variant—quickly overtook the original virus as the predominant cause of COVID. *Id.* ¶ 83. Instead of admitting that it did not, and could not, know whether its vaccine was effective against Delta, Pfizer told the public in spring and summer 2021 that its vaccine was “very effective, around 90%” against Delta, and that it was “very, very, very effective against Delta.” *Id.* ¶¶ 88.

These misrepresentations were particularly egregious in light of the actual facts. Pfizer’s entire clinical trial was conducted prior to Delta’s emergence. *Id.* ¶ 95. For that reason, FDA recognized there was no telling whether Pfizer’s vaccine possessed “effectiveness against SARS-CoV-2 variants” like Delta. *Id.* Indeed, even as late as September 2021, Pfizer’s data about Delta was limited to an “exploratory” data set of only twenty-three people that FDA characterized as “very limited.” *Id.* ¶ 121. Meanwhile, public studies suggested that the vaccine had little to *negative* effect against the Delta variants. *Id.* ¶¶ 110–16. Data from the U.K. and Scotland, for example, showed that during Delta a greater percentage of vaccinated were dying from COVID than unvaccinated. *Id.* ¶¶ 114–16.

**(5) Censorship:** Finally, Pfizer engaged in a coordinated campaign to censor and intimidate critics of its vaccine. *Id.* ¶¶ 125–38. Pfizer had unique access to prominent social media companies, and used that access to demand that the companies censor prominent scientists and other stakeholders who raised reasonable and fact-based questions about its vaccine’s efficacy. For example, Pfizer feared that former FDA Director Brett Giroir’s belief in natural immunity would “driv[e] news coverage” and be “corrosive” to the public confidence in Pfizer’s vaccine. *Id.* ¶¶ 132–33. Pfizer thus encouraged social media companies to censor Giroir. *Id.* ¶ 133.

### STANDARD OF REVIEW

“In determining whether to grant a motion to dismiss the district court must not go outside the pleadings and must accept all well-pleaded facts as true, viewing those facts most favorably to

the plaintiff.” *Scanlan v. Texas A&M Univ.*, 343 F.3d 533, 536 (5th Cir. 2003). Courts in this district regularly refuse to take judicial notice of online publications to “challenge Plaintiffs’ factual allegations” because the contents of such articles “are not indisputably true.” *Linenweber v. Sw. Airlines Co.*, No. 3:20-CV-00408-K, 2023 WL 6149106, at \*4 (N.D. Tex. Sept. 19, 2023); *Jefferson v. Certain Underwriters At Lloyd's London*, 658 F. App’x 738, 744 (5th Cir. 2016) (similar for press releases) (quoting Fed. R. Evid. 201(b)).

## ARGUMENT

### I. THE STATE’S CLAIMS ARE NOT PREEMPTED.

It is well-established that in pharmaceutical regulation, “Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness,” *Merck Sharp & Dohme Corp. v. Albright*, 587 U.S. 299, 311 (2019), and that “Congress has repeatedly declined to pre-empt state law,” *Wyeth v. Levine*, 555 U.S. 555, 581 (2009). State law commonly provides a valid cause of action against products regardless of whether they are FDA-approved. *See Medtronic v. Lohr*, 518 U.S. 470 (1996). Nothing about the PREP Act or the FDCA changes that as regards Pfizer’s vaccine.

#### A. The PREP Act Does Not Preempt the State’s Consumer Protection Claims Because the DTPA Is Not “Different From, or in Conflict With” Federal Law.

The PREP Act does not preempt the State’s claims because DTPA claims for misrepresentations are not “different from, or in conflict with” similar federal statutes or “any requirement” under the Act. *Contra* Mot. at 12-14. The PREP Act’s single preemption provision specifies that:

[N]o State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that—

(A) is different from, or in conflict with, any requirement applicable under this section; and

(B) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, or any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this chapter, or under the Federal Food, Drug, and Cosmetic Act.

42 U.S.C. § 247d-6d(b)(8). The Court’s preemption analysis must be limited to the statutory text. *See Cipollone v. Liggett Grp.*, 505 U.S. 504, 517 (1992) (when statute contains express preemption provision, the statute’s “pre-emptive scope” is “governed entirely by the express language”). Here, the text of this provision defeats Pfizer’s preemption argument because it applies only to state laws that are “*different* from, or in *conflict* with, any requirement applicable” under the PREP Act. § 247d-6d(b)(8)(A) (emphasis added). Nothing about Texas’ consumer protection claims asserted here are “different from, or in conflict with” the scope of the PREP Act, nor with any aspect of federal law altogether.

Pfizer overlooks the incontrovertible fact that the claims alleged in the Complaint mirror available federal ones. The federal “Covid-19 Consumer Protection Act made it illegal ‘for any[one] to engage in a deceptive act or practice in or affecting commerce in violation of section 5(a) of the [FTC] Act (15 U.S.C. 45(a)) that is associated with the treatment, cure, prevention, mitigation, or diagnosis of covid-19.’” *Romero*, 2022 WL 4095424, at \*4. And the State’s first four DTPA claims all concern “deceptive act[s] or practice[s] . . . associated with the treatment” and “prevention” of “covid-19.” *Id.*<sup>4</sup> Furthermore, the DTPA expressly references FTC Act section 5 and instructs courts to construe the DTPA and FTC Act harmoniously. DTPA § 17.46(c)(1). This

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<sup>4</sup> The fifth DTPA claim pled, regarding censorship, also is not preempted because it has nothing to do with “design, development, clinical testing,” etc. 47 U.S.C. § 247d-6d(b)(8)(B).

action is accordingly a far cry from one that is “different from, or in conflict with” any federal laws. 47 U.S.C. § 247d-6d(b)(8)(A). Where, as here, state “law only mirrors federal . . . law,” there “is no reason to conclude that Congress intended to preempt the state law.” *State of Ill. v. Panhandle Eastern Pipe Line*, 935 F.2d 1469, 1479 (7th Cir. 1991). For this reason alone, Pfizer’s PREP Act preemption argument fails.

Pfizer claims the State’s suit is preempted because it “seeks to hold the company liable under state law for actions ‘relating to’” its vaccine. Mot. at 14. But the PREP Act’s preemption provision does not preempt all actions that relate to its vaccine; rather, such actions are preempted only if they **additionally** are “different from, or [are] in conflict with” federal law. 42 U.S.C. § 247d-6d(b)(8)(A). And the State’s actions here are not. Indeed, in many respects the State’s claims are premised on Pfizer’s complete disregard of FDA’s explanation to Pfizer of what its data supported. FDA told Pfizer it did not have adequate data to make several representations that it nevertheless went on to tell the public. *Compare, e.g.,* Compl. ¶ 49 (FDA’s finding: “[I]t is *not possible* to assess sustained efficacy over a period longer than 2 months.”), *with id.* ¶ 76 (Pfizer’s misrepresentation: “At 6 months [from vaccination,] the protection is robust.”). The State is not preempted from enforcing against those misrepresentations. *See, e.g., Jacob v. Mentor Worldwide*, 40 F.4th 1329, 1338 (11th Cir. 2022) (no preemption of claim where state law claim relies on “violation of federal requirements as evidence that [manufacturer] violated state law”).

The PREP Act’s preservation of State claims not “different from, or in conflict with” federal law is a well-established concept in the Supreme Court and the Fifth Circuit, particularly for federally regulated products. For example, federal law expressly preempts state laws “different from, or in addition to” federal laws for medical devices. 21 U.S.C. § 360k(a). But courts routinely permit state law claims against medical device manufacturers provided the claims do not rely on

“conflicting state statutes and regulations.” *Medtronic*, 518 U.S. at 489 (state negligence action against manufacturer); *see also, e.g., Borskey v. Medtronics, Inc.*, 105 F.3d 651, 651 (5th Cir. 1996) (“To the extent that the appellants’ state law actions set forth violations of federal requirements, they are not preempted.”). Similarly, federal law governing pesticides preempts state laws “in addition to or different from” federal requirements. 7 U.S.C. § 136v(b). But the courts routinely permit State law claims “fully consistent with federal requirements” to go forward against pesticide manufacturers, including claims related to efficacy. *Bates v. Dow Agrosciences*, 544 U.S. 431, 449 (2005) (materially similar, for federal pesticide law). Under these circumstances, the law is clear that Texas is not prohibited from enforcing the DTPA against Pfizer’s misrepresentations. *See, e.g., Jacob v. Mentor Worldwide*, 40 F.4th 1329, 1338 (11th Cir. 2022) (no preemption where state law claim relies on a “violation of federal requirements as evidence that [manufacturer] violated state law”).

**B. The FDCA Does Not Preempt the State’s Claims Because Congress Deliberately Did Not Preempt State Claims Against Drug Manufacturers .**

The FDCA likewise does not preempt the State’s claims. Although FDA is charged under the FDCA with approving drug products, *see, e.g.,* 21 U.S.C. § 355, the Supreme Court has held that generally, the FDCA does not preempt state law claims. *Wyeth v. Levine*, 555 U.S. 555, 573 (2009) (holding there is simply “no merit” to the “argument” that FDA approvals shield manufacturers from “comply[ing] with a state-law duty”).<sup>5</sup> “Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness”—rather, “all evidence of Congress’ purposes is to the contrary.” *Id.* at 575, 574. In enacting the FDCA, Congress recognized that “state-law remedies further consumer protection by motivating

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<sup>5</sup> Congress added a preemption clause to the FDCA that “applies only to medical devices” and the Supreme Court has recognized that “Congress *could* have applied the pre-emption clause to the entire FDCA,” but did not do so. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 327 (2008).

manufacturers to produce safe and effective drugs.” *Id.* That is why suits under state law are common against FDA-approved products, including against advertising that is “false and misleading as to efficacy.” *Delarosa v. Boiron, Inc.*, No. 10-1569-JST (CWX), 2011 WL 13130856, at \*3 (C.D. Cal. Dec. 29, 2011) (no preemption); *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 546 F.Supp.3d 1284, 1308 (S.D. Fla. 2021) (materially similar).

Pfizer protests, however, that “FDA[] [has the] exclusive right to enforce the FDCA.” Mot. at 16. That is technically true, but irrelevant. It is technically true because no “private right of action exists” under the FDCA. *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997). But it is irrelevant because the State’s claims arise under *state* law, Compl. ¶¶ 152–70, and because “Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness,” *Merck Sharp & Dohme Corp. v. Albright*, 587 U.S. 299, 311 (2019). FDCA standards are commonly enforced through *state* law causes of action. *In re MDL 2700 Genentech Herceptin*, 960 F.3d 1210, 1234 (10th Cir. 2020) (no preemption where “federal regulatory standard is precisely the same as the state law standards sought to be imposed by the plaintiffs”).

Pfizer also argues in multiple respects that the State’s lawsuit is an attack on FDA’s decision to approve its vaccine as safe and effective. Mot. At 15–18, 4–8. At the outset, Pfizer’s improper reliance on non-judicially noticeable documents outside the Complaint forecloses consideration of these arguments. *Linenweber*, 2023 WL 6149106, at \*4. But in any event, this misunderstands the State’s complaint, which focuses on misleading representations to *the public*, not FDA’s approval decisions.

For example:

(1) Pfizer, citing Paragraph 144 of the Complaint, claims the State argues that “FDA ‘engaged in an artificial and flawed consideration and balance of Pfizer’s vaccine’s benefits and

risks.” Mot. at 15–16. But paragraph 144 actually states: “Pfizer’s misrepresentations resulted in the public engaging in an artificial and flawed consideration and balancing of Pfizer’s vaccine’s benefits and risks . . . . Had the public known the truth about the efficacy of Pfizer’s COVID-19 vaccine, a substantial portion would likely have opted for an alternative or foregone inoculation altogether.”

(2) Pfizer also claims the State’s “complaint second guesses FDA’s decision making” and then invokes case law where a plaintiff “in substance, challenged FDA’s decision to permit defendant’s unapproved drug to remain on the market.” Mot. at 17, 18. But the complaint repeatedly endorses FDA’s findings as evidence, including that “FDA went out of its way to expressly state that Pfizer’s results did not support several important vaccine characteristics that are highly relevant to Pfizer’s representations to the public.” Compl. ¶ 49.

The bottom line is this: The State takes no issue with FDA’s determination to grant Pfizer an EUA and, later, other approvals. Instead, the State’s Complaint contains well-pled factual allegations focusing on Pfizer’s gross misrepresentations to the public about specific aspects of its vaccine’s performance, and that is not preempted. *See Louisiana v. Pfizer, Inc.*, No. 3:13-CV-00727-BAJ-RL, 2014 WL 3541057, at \*7 n.3 (M.D. La. July 17, 2014) (state lawsuit against Pfizer not preempted by FDCA when the State did not challenge the FDA’s approval, but rather sought “damages for Pfizer’s alleged intentionally false, fraudulent, and misleading conduct”). Indeed, many of Pfizer’s representations contradicted *precisely* what FDA found in its formal EUA memorandum. *See supra* at 7–10. It would be little different than if Pfizer represented that its vaccine cured cancer. And that is surely something that the State can enforce against.

Pfizer further claims the “95% efficacy” claim shows the State is “challenging federal regulatory and policy decisions.” Mot. at 18. Pfizer contends that “FDA itself uses the 95% relative

risk reduction claim” in “[1] the vaccine’s licensing memorandum, [2] the facts sheets provided to patients and physicians, and [3] other communications with the public.” *Id.* But this misstates the public record and represents another improper attempt to contradict the State’s well-pled allegations.<sup>6</sup> Indeed, FDA’s own guidance indicates that “relative risk reduction” statistics are likely to mislead.<sup>7</sup> *See supra* at 8–9. FDA further clarified that whenever a manufacturer *does* use that statistic, it should also “[p]rovide absolute risks, not just relative risks.” *Id.* And no Pfizer press release or other public statement ever mentioned that its vaccine’s absolute risk reduction was less than 1%. Compl. ¶ 45. At best, Pfizer has created a factual dispute unresolvable on the pleadings. Compl. at ¶ 48.

Even if FDA’s public communications endorsed Pfizer’s “95% efficacy” claim, they would still not preempt state law because only agency action “with the force of law can pre-empt conflicting state requirements.” *Wyeth*, 555 U.S. at 576. That typically includes only regulations formally promulgated with a notice-and-comment period, and does not include letters, fact sheets, or other informal agency pronouncements. *See, e.g., Reid v. Johnson & Johnson*, 780 F.3d 952, 964 (9th Cir. 2015) (FDA letter with “enforcement guidelines” did not “carry the force of law” sufficient to preempt state law); *Fellner v. Tri-Union Seafoods, L.L.C.*, 539 F.3d 237, 256 (3d Cir. 2008) (similar).

None of the FDA materials Pfizer urges this court to rely on regulate “with the force of

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<sup>6</sup> FDA’s current “fact sheet” for patients makes *no* mention of relative risk reduction, much less 95% efficacy. Instead, it just says that “the totality of the scientific evidence available show[ed] that the product *may* be effective to prevent COVID-19.” *See* FDA, *Pfizer-BioNTech Covid-19 Vaccine Fact Sheet*, <https://www.fda.gov/media/167212/download?attachment>.

<sup>7</sup> In fact, in 2020, FDA’s Commissioner was excoriated for using “relative risk reduction” instead of “absolute risk reduction” when describing the efficacy of COVID treatments—so much so that he had to apologize. *See* PBS, *FDA Chief Apologizes for Overstating Plasma Effect on Coronavirus* (Aug. 25, 2020), <https://www.pbs.org/newshour/health/fda-chief-apologizes-for-overstating-plasma-effect-on-coronavirus>.

law.” *Wyeth*, 555 U.S. at 576. They were not subject to public notice-and-comment and followed no “formal administrative procedure.” *Hardeman*, 997 F.3d at 957. So they have no import for the preemption question. Finally, even if Pfizer were right (it is not) about the 95% efficacy claim, that is only *one* of the State’s five DTPA claims here. *See supra* at 8–11. The viability of the 95% efficacy claim has no bearing on whether the other claims are preempted.

The FDCA does not preempt state claims; it welcomes them. It is no bar to a DTPA claim for deceptive statements.

## II. PFIZER DOES NOT HAVE IMMUNITY FOR MISREPRESENTATIONS

Pfizer also does not have immunity for the misrepresentations laid out in the complaint because the PREP Act immunizes only claims for “loss” (physical harm or mental anguish) resulting from the “administration . . . of a covered countermeasure” (here, the injection of a vaccine) to an “individual.” 47 U.S.C. § 247d-6d(a)(1). In plain terms, it grants Pfizer immunity from personal injury claims from individuals that received Pfizer’s vaccine. It does not touch a government’s power to bring a *parens patriae* action based on misleading marketing claims.

The PREP Act’s immunity provision provides that:

Subject to the other provisions of this section, a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure.

47 U.S.C. § 247d-6d(a)(1). The Court must interpret this language according to the limitations in its plain text. *Mitchell v. Advanced HCS, L.L.C.*, 28 F.4th 580, 587 (5th Cir. 2022) (interpreting PREP Act immunity based on its “plain text”). In doing so, several courts have already recognized that the PREP Act does not provide an unqualified grant of immunity from state claims. *See, e.g., Lollie v. Colonnades Health Care Ctr. Co.*, 2021 WL 4155805, at \*3 (S.D. Tex. Sept. 13, 2021);

*Est. of Maglioli v. Andover Subacute Rehab. Ctr.*, 478 F.Supp.3d 518, 529 (D.N.J. 2020).

The plain text of the PREP Act’s immunity provision clearly indicates that it does not foreclose the State’s suit, for three reasons:

*First*, PREP Act immunity only extends to claims “for loss.” 47 U.S.C. § 247d-6d(a)(1). The statute defines loss to include specific ailments that equate to the traditional definition of personal injury. *Id.* § 247d-6d(a)(2)(A) (“death,” “physical, mental, or emotional injury,” *etc.*). But the State’s claims are not ones “for loss” as defined. Indeed, under the DTPA the State does not need to prove “loss” at all. It can bring a suit “[w]hensoever” it “has reason to believe that any person is engaging in, has engaged in, or is about to engage in” any false, misleading, or deceptive conduct in trade or commerce, and the State concludes such action “would be in the public interest.” DTPA § 17.47(a); *see also id.* § 17.46(a). (Consumers, by contrast, can bring a DTPA action only if they have suffered “economic damages” or “mental anguish.” *Id.* § 17.50(a).)

Here, the State’s first four DTPA claims are about misrepresentations unrelated to physical or mental “loss” suffered from vaccine side effects. *See* Compl. ¶¶ 154–67. The State’s fifth DTPA claim concerns Pfizer’s schemes to conceal the truth. *Id.* ¶¶ 168–70. The harm alleged is that Pfizer’s misrepresentations “prevented and hindered the public from obtaining information material to properly balancing the benefits and risks of its vaccine,” thus “distort[ing] the risk/benefit analysis in Pfizer’s favor by artificially inflating the vaccine’s perceived efficacy.” Compl. ¶ 141. None of this relates to the statutory “loss” definition or personal injury.

*Second*, the PREP Act’s immunity language blocks only claims “from the administration” of a covered product to “an individual.” 47 U.S.C. § 247d-6d(a)(1). This further underscores that the immunity is for personal injury suits, not sovereign consumer protection suits in the public interest. Texas is not suing about “administration” of the Pfizer vaccine, much less administration

of the vaccine to “an individual.” Instead, the State is enforcing its consumer protection statutes in its “*parens patriae*” capacity. *Hood ex rel. Mississippi v. JP Morgan Chase*, 737 F.3d 78, 81 (5th Cir. 2013). When the State brings such suits, it is acting in a quasi-sovereign capacity on behalf of the public interest of its citizens. *See, e.g., Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel. Barez*, 458 U.S. 592, 602 (1982) (*parens patriae* suits are based on “quasi-sovereign interests” that “the State has in the well-being of its populace”). “[T]he State” itself—not an individual—“is the real party in interest.” *People by Underwood v. LaRose Indus.*, 386 F. Supp. 3d 214, 218 (N.D.N.Y. 2019). And the State is “authorized to file suit independently of any consumer complaints, as a *parens patriae*.” *West Virginia ex rel. McGraw v. CVS Pharmacy, Inc.*, 646 F.3d 169, 175–76 (4th Cir. 2011). A State *parens patriae* action based on consumer deception is thus well outside the scope of the PREP Act’s individual immunity.

*Third*, PREP Act immunity cannot plausibly be read to cover governmental suits for misrepresentations because such a result would lead to numerous absurdities. *See Dunn-McCampbell Royalty Int., Inc. v. Nat’l Park Serv.*, 630 F.3d 431, 439 (5th Cir. 2011) (courts “should avoid any interpretation that would lead to absurd or unreasonable outcomes”) (citation omitted). The PREP Act immunity provision provides immunity against both State *and* Federal claims. 47 U.S.C. § 247d-6d(a)(1). That means if Pfizer is immune from the State’s claims about misrepresentations, then not even the federal government—including FDA—could sue. Drawn out to its logical conclusion, that would allow Pfizer to claim its vaccines cure cancer with *no* consequences from the federal government or anyone else. That is absurd, and not even Pfizer believes it. *See* Mot. at 14 (contending instead that “FDA has the exclusive authority to enforce the FDCA’s requirements”). The Supreme Court requires “language much plainer than the text” of the PREP Act before a court could conclude that Congress intended “the perverse effect of

granting complete immunity” in such situations. *Medtronic*, 518 U.S. at 487.<sup>8</sup> This is a case about how Pfizer’s misstatements led Texas consumers to make choices they would not have otherwise made, and Pfizer’s censorship of scientists that set the record straight. Pfizer enriched itself based on these misleading statements to the tune of billions of dollars. None of that relates to a “claim for loss” from the “administration” of Pfizer’s vaccine to an “individual.” Pfizer is not immune.

### III. THE STATE HAS PLED VIABLE DTPA CLAIMS

The State has plausibly alleged each required element of a DTPA claim for all five counts against Pfizer. To plead a DTPA claim, the State must plausibly allege Pfizer “is engaging in, has engaged in, or is about to engage in any act or practice” unlawful under the DTPA, and that the State’s lawsuit “would be in the public interest.” DTPA § 17.47(a). An act or practice violates the DTPA if it is “[f]alse, misleading, or deceptive” and occurred “in the conduct of any trade or commerce.” DTPA § 17.46(a). The DTPA is “construed liberally to promote its central purpose” of protecting Texas consumers. *Miller v. Keyser*, 90 S.W.3d 712, 715 (Tex. 2002).

The State’s complaint easily satisfies that standard, as explained in Background Section D. Pfizer does not meaningfully contest that the State’s complaint contains “sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.” *Gonzalez v. Kay*, 577 F.3d 600, 603 (5th Cir. 2009). Instead, Pfizer raises three statutory arguments in rebuttal. All fail.

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<sup>8</sup> Pfizer’s two cases (Mot. at 12) purporting to hold that PREP Act immunity blocks misrepresentation claims are not even in the ballpark because they both concern personal injuries sustained from the administration of the Pfizer vaccine, not misleading marketing statements. In *Gibson v. Johnson & Johnson*, 2023 WL 4851413 (E.D. Pa. July 28, 2023), the plaintiff, an incarcerated *pro se* litigant, complained that he was “misled” into “accepting the administration” of a COVID vaccine, resulting in “serious physical and psychiatric adverse effects” from receiving the vaccine. *Id.* at \*2. As such, it was a claim “for loss”—the normal situation calling for PREP Act immunity. And in *M.T. ex rel. M.K. v. Walmart Stores*, 528 P.3d 1067 (Kan. Ct. App. 2023), the court just concluded that a mother could not sue for improper administration of a vaccine to her daughter, and that her “misrepresentation” claims were in fact disguised claims about “alleged improper administration of a covered countermeasure,” *id.* at 1079.

1. Pfizer claims its misrepresentations had no effect on “trade” or “commerce” within the meaning of the DTPA because the U.S. government paid for the Pfizer vaccine, and consumers got it for free. Mot. at 20. But Texas courts have long held that goods or services provided for free can still violate the DTPA. “It is immaterial whether [defendants] provide[] a service in exchange for money; the statute as a whole supports the conclusion that transfer of valuable consideration is not necessary.” *Mother & Unborn Baby Care of N. Texas, Inc. v. State*, 749 S.W.2d 533, 538 (Tex. App. 1988), *writ denied* (Nov. 16, 1988). Pfizer’s brief neglects to mention that its only cited case to the contrary, *Word of Faith World Outreach Ctr. Church, Inc. v. Morales*, 787 F.Supp. 689, 697 (W.D.Tex. 1992), was overturned by the Fifth Circuit. *See Word of Faith World Outreach Ctr. Church, Inc. v. Morales*, 986 F.2d 962, 969 (5th Cir. 1993) (reversing the trial court’s holdings interpreting the DTPA).<sup>9</sup>

Nor does it matter that Pfizer sold its vaccine to the U.S. government instead of direct to consumers, because that sale and the later distribution of Pfizer vaccines in Texas both fit squarely with the DTPA’s definition of “trade” and “commerce.” The DTPA defines “trade” and “commerce” to include, among other things, the “advertising, . . . sale, . . . or distribution of any good or service . . . and shall include any trade or commerce directly or indirectly affecting the people of this state.” DTPA § 17.45(6). Pfizer’s sale and distribution of its vaccine in Texas thus qualifies as an act of “trade” or “commerce” in at least three ways: Pfizer directly advertised its vaccine in Texas; Pfizer distributed its vaccine to millions of Texans; and Pfizer’s sale of vaccines “directly [and] indirectly affect[ed] the people of” Texas. Pfizer’s own brief concedes the

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<sup>9</sup> In ordering the district court to abstain from adjudicating state law issues under *Railroad Comm’n v. Pullman Co.*, 312 U.S. 496 (1941), the Fifth Circuit vacated the lower court’s finding as to “whether the investigative powers provided the Attorney General by the DTPA . . . may be invoked against” an organization providing free services. 986 F.2d at 969.

“ordinary meaning” of “distribution” applies to its Texas distribution of vaccines. Mot. at 21 n.22. The only case it cites to the contrary (at 21 n.22) is inapposite, as it dealt with a different phrase in a different statute, and in any event, held the ordinary meaning of that word should be used.

Additionally, a DTPA defendant does not need to sell its product directly to the consumer. In consumer DTPA lawsuits, the Texas Supreme Court has held that “[p]rivacy between the plaintiff and defendant is not a consideration . . . The only requirement is that the goods or services sought or acquired . . . form the basis of his complaint.” *Flenniken v. Longview Bank & Tr. Co.*, 661 S.W.2d 705, 707 (Tex. 1983). That logic applies with at least equal force to an Attorney General DTPA lawsuit, where the state represents its own state interests in a *parens patriae* capacity, not the interests of individual consumers. *See supra* Section II (discussing *McGraw*).

Finally, Pfizer’s claim that its misleading statements “took place long after Pfizer contracted to provide hundreds of millions of doses” is both inapposite and wrong. Mot. at 22. It is *inapposite* because under the DTPA, “there is no requirement that the defendant’s unconscionable act occur simultaneously with the sale or lease of the goods or services that form the basis of the consumer’s complaint.” *Flenniken*, 661 S.W.2d at 707. It is also *wrong*, because Pfizer’s misrepresentations resulted in several additional billion dollars of revenue after they were made. As alleged, Pfizer’s original, pre-vaccination sale was for only \$1.95 billion and 100 million doses. Compl. ¶ 53. By making misrepresentations about the vaccine’s efficacy, Pfizer created huge consumer demand for its vaccine that resulted in the U.S. government exercising its option for an additional 500 million doses, earning an additional \$10.05 billion. Compl. ¶ 147. This artificially inflated consumer demand led the federal government to execute a new contract for an additional \$3.2 billion of vaccines in 2022. Compl. ¶ 148. As the market leader for COVID-19 vaccines—a market position established at least in part due to its misrepresentations—Pfizer

continues to sell its vaccine directly to the public and to consumers. Compl. ¶ 151.

2. Pfizer’s claim (at 22) that its misrepresentations were not related to any “consumer transaction” is irrelevant because the DTPA does not require that lawsuits brought by the Attorney General involve a “consumer.” While “[a]n aggrieved *individual*” seeking to bring suit “must meet the statutory definition of ‘consumer,’” that “issue is not applicable where the cause of action is brought by the AG.” *Household Retail Servs., Inc. v. State*, No. 04-00-00734-CV, 2001 WL 984779, at \*3 n.4 (Tex. App. Aug. 29, 2001) (emphasis added) (comparing DTPA § 17.50 (consumer lawsuits) to DTPA §§ 17.46(a), 17.47(a) (Attorney General lawsuits)). That is because the DTPA’s definition of “consumer” “only describes the class of persons entitled to bring suit under section 17.50 [the consumer cause of action]; it does not define the class of persons subject to liability under the DTPA.” *Flenniken*, 661 S.W.2d at 706. The Attorney General can bring suit against “[a]ny person engaging in such deceptive practices,” if he determines the suit is in the public interest. *Riverside Nat. Bank v. Lewis*, 603 S.W.2d 169, 173 (Tex. 1980) (citing DTPA § 17.47(a)). Preventing misrepresentations that warp Texans’ medical decisions is plainly in the public interest, and Pfizer does not contend otherwise.

3. Finally, Pfizer’s claim (at 25) that the State’s allegations are implausible would require this court to ignore dozens of pages of well-pleaded statistics from Pfizer’s own data and FDA, as well as Pfizer’s own public statements, without explanation. The State’s complaint specifically identifies several claims about vaccine efficacy that FDA told Pfizer *not* to make—and several instances where Pfizer publicly made those claims anyway. That is misrepresentation under the DTPA, and it is well-pled. This court should deny the motion.

## CONCLUSION

The Court should deny Pfizer’s Motion to Dismiss.

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Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I certify that on April 29, 2024, a copy of the foregoing document was served via the Court's electronic filing system to all counsel of record.

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